UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, ex rel. CONSTANCE A. CONRAD,	)	
Plaintiffs,	)	
	)	Civil Action
	)	No. 02-11738-RWZ
vs.	)	
ABBOTT LABORATORIES, INC., et al.,	)	
Defendants.	)	

MOTION HEARING

BEFORE THE HONORABLE RYA W. ZOBEL
UNITED STATES DISTRICT COURT JUDGE

UNITED STATES DISTRICT COURT
John J. Moakley U.S. Courthouse
1 Courthouse Way
Boston, Massachusetts 02210
November 8, 2012
2:30 p.m.

* * * *

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P R O C E E D I N G S

(The following proceedings were held in open court before the Honorable Rya W. Zobel, United States District Judge, United States District Court, District of Massachusetts, at the John J. Moakley United States Courthouse, 1 Courthouse Way, Boston, Massachusetts, on November 8, 2012.)

THE COURT: Good afternoon. Please be seated.

COURTROOM DEPUTY CLERK URSO: This is the United States versus Mid-Atlantic, Civil Action No. 02-11738. If counsel could identify themselves, please, for the record.

MR. LEFKOWITZ: Jay Lefkowitz for the defendants, and arguing for the group of defendants in the primary motion to --

THE COURT: Now, whom do you represent?

MR. LEFKOWITZ: I represent Teva --

THE COURT: Because my list is by defendants and by plaintiffs.

MR. LEFKOWITZ: I represent Teva Pharmaceuticals and a couple of the subsidiaries, Goldline Laboratories as well and Duramed Pharmaceuticals.

THE COURT: Wait one second. I need to organize this. We have pages and pages of lawyers.

(Pause.)

THE COURT: Okay. It's not Abbott, right?

MR. LEFKOWITZ: No. It's -- starting at the top of

the caption, the first one I have as mine is Duramed.

THE COURT: Got you. Mr. Lefkowitz, right?

MR. LEFKOWITZ: Correct. And then three down from Duramed, I'm also representing Goldline.

THE COURT: That's okay. I only need the one.

MR. LEFKOWITZ: Okay. Thank you, your Honor.

THE COURT: How about you?

MR. DEL MONACO: John Del Monaco, with the same firm as Mr. Lefkowitz and the same defendants.

THE COURT: Del Monaco. Okay. Got it.

MR. DOVE: I'm Ronald Dove, your Honor. I represent Defendant Healthpoint and a number of the other defendants, but I'm here to argue the second motion, Healthpoint's motion to dismiss.

THE COURT: How come we have so many motions to dismiss again and again and again by the same defendants?

MR. DOVE: Your Honor, this is our second motion. Our first motion was in the case brought by the United States and this is our first motion in this case.

MR. RODDY: John Roddy for --

THE COURT: Wait a minute. I was looking for Healthpoint. I know you guys only got 15 minutes to argue, but I have at least half an hour to find you.

(Pause.)

THE COURT: Mr. Dove, I found you.

MR. RODDY: John Roddy, Bailey & Glasser for the relator. I will be arguing. With me is --

MS. RYAN: Elizabeth Ryan. Good afternoon, your Honor.

MR. BOYLE: Good afternoon, your Honor. Leo Boyle --

THE COURT: Hold it. Hold it.

I'm sorry, you are Mr.?

MR. RODDY: Roddy, your Honor, for the relator.

THE COURT: Why don't I find you?

COURTROOM DEPUTY CLERK URSO: Did you find him, Judge?

THE COURT: Okay. I have Mr. Roddy. And you are?

MS. RYAN: Good afternoon, your Honor. Elizabeth Ryan, also with Bailey & Glasser.

THE COURT: Okay.

MR. BOYLE: Good afternoon, your Honor. Leo Boyle, also for the relator.

THE COURT: Got you.

Now, anybody else who is arguing?

MR. EVANS: Good afternoon, your Honor. James Evans for Cypress and Hawthorn.

THE COURT: But you're not arguing?

MR. EVANS: We do have a motion to dismiss, your Honor.

THE COURT: Well, I understand that, but not a

separate one?

MR. EVANS: No. It is an individual one and it was noticed for the hearing today.

THE COURT: Who is your client?

MR. EVANS: Cypress and Hawthorn.

THE COURT: Hybrid, did you say?

MR. EVANS: Hawthorn and Cyprus.

(Discussion off the record at the Bench.)

COURTROOM DEPUTY CLERK URSO: Was your motion dealt with?

MR. EVANS: I believe it's still outstanding. It's Docket No. 326 and I know that --

THE COURT: I think that was done.

COURTROOM DEPUTY CLERK URSO: Yes.

MR. RODDY: Your Honor, I don't have the docket or the document in front of me, but I believe it was with respect to certain discrete drugs and the relator had agreed to dismiss the claims against those particular drugs. I did not think that was on for today.

THE COURT: Yes, I didn't either. So, did that happen? Did the relator, in fact, dismiss as to those drugs?

MR. RODDY: The relator filed a response that said we will dismiss as to those drugs, and I believe that was entered on the docket and I honestly can't recall. Procedurally it was quite a number of months back.

THE COURT: I think under the circumstances we will pass that motion since we think it's already gone.

MR. EVANS: Thank you, your Honor.

THE COURT: Thank you. Anybody else?

(No response.)

THE COURT: Okay. Now, what we have is a consolidated motion by defendants to dismiss the tenth amended complaint. There is a separate little supplemental one by Abbott Laboratories with its own special, and then there is Healthpoint's motion to dismiss. Those are the only motions that I'm aware of that we are to hear today; is that correct?

MR. BALASSA: Your Honor, Gabor Balassa for Abbott Laboratories.

We did not understand our motion was being heard today and we understood that the relator had dismissed complaints with respect to the products that were at issue in our separate motion to dismiss.

THE COURT: So, that's finished now?

MR. RODDY: That's correct. Again, your Honor, I believe it was one or two discrete products out of the entire range and those were enumerated in relator's response to Abbott's motion to dismiss saying we would not contest that motion to dismiss.

THE COURT: So, that is No. 335. And the parties agree that these particular products are not implicated in any

wrongdoing?

MR. RODDY: Yes, your Honor.

THE COURT: Okay.

Does that mean that Abbott is also out of the joint motion?

MR. BALASSA: No, your Honor. We have other products that are part of the joint motion.

THE COURT: Okay. So, I guess we go to Mr. Lefkowitz for the joint motion.

MR. LEFKOWITZ: Thank you, your Honor.

THE COURT: And then Healthpoint for its separate motion, right?

MR. DOVE: Correct, your Honor.

MR. LEFKOWITZ: So, good afternoon, your Honor.

In light of the window of time that we have this morning -- this afternoon, if the Court would permit --

THE COURT: You don't get charged with the time that I have spent trying to find you.

MR. LEFKOWITZ: That's quite all right.

I think I can make my argument in about eight or nine minutes, maybe ten, and then I'd to just be in a position to stand up at the end and respond for just about two minutes, if I may.

In addition, because there's been extensive briefing here, I'm going to focus on what I think are the most critical

things that have not necessarily been elucidated in the briefing.

Number one, I want to just make a few key points and show you a couple of things with respect to the jurisdictional issue, the public disclosure bar, and then I'd like to make one or two points that arise out of the *Organon* and the *Healthpoint* decisions that your Honor has issued since the briefing and we'll rest on our motion with respect to everything else.

Just very briefly, Ms. Conrad is alleging that the defendants caused states to submit false claims to the Federal Government by falsely representing that certain products were eligible for federal reimbursement and that then the states reimbursed drugstores for those purchases and then requested matching federal funds. That's the essence of the alleged fraud.

Now, from a jurisdictional perspective, as your Honor knows well, because Ms. Conrad doesn't claim to be an original source, there's no jurisdiction if there was a prior public disclosure of the facts on which her allegations are based, and as you made clear most recently in *Organon*, the first test in the First Circuit is whether the essential elements exposing the particular transactions as fraudulent find their way into the public domain, and you explain that that happens when both the alleged misrepresented state of facts and the

alleged true state of facts are publicly available. So, what I want to do for just the next few minutes is show you exactly how that's the case publicly.

And if I may, I want to take a first look at what I've highlighted here, which is one of the publicly-available sources. This is a selection of what you would see if you went online to the CMS, the government center for Medicaid services, Medicaid and Medicare services database. This is a drug product data report. I'll wait until the -- if the Court would like, I have a -- I can give the Court a hand-up like this.

THE COURT: Turn on the public one.

COURTROOM DEPUTY CLERK URSO: It should be on. It was on and then they said something happened.

THE COURT: My monitor isn't going on.

COURTROOM DEPUTY CLERK URSO: Your monitor?

THE COURT: With which I decide what you get to see.

MR. LEFKOWITZ: I have a hand-up if that would be easier.

THE COURT: No. I was trying to show it on the big screen so that everybody in the courtroom could see what you're doing.

COURTROOM DEPUTY CLERK URSO: It's on. I don't know why it's not coming on.

(Discussion off the record.)

THE COURT: Well, we'll have to proceed as we --

MR. LEFKOWITZ: Okay. May I hand up a hardcopy? I don't need it. I can see the screen. Can you see it as well? Okay.

If I may, your Honor. So, what I want to show you here is the first of the three different core set of publicly-available documents that would allow anyone -- and I was able to do this literally from my iPad -- to find the relevant information that would disclose both the false set of facts and the true state of events. This is what --

THE COURT: Now, what's the date of this report?

MR. LEFKOWITZ: This report is basically a current report. You can -- it's updated all the time and, of course, you can find out historical by going to the hardcopies.

This shows what drugs a company -- in this case I took Teva Pharmaceuticals -- has listed as a covered outpatient drug for purposes of getting reimbursement, and I have simply taken one line here and I've highlighted to demonstrate that by looking at this data, you could see that a called drug called Zolpidem, which is -- happens to be the generic of Ambien, the sleeping pill, was submitted by Teva Pharmaceuticals to the states for purposes of reimbursement under Medicaid.

Now, if I go to the next slide, this is a different federal document. This is the CMS drug utilization data

report, and what this shows is that with respect to the state of Massachusetts over in the left-hand column, it refers to Zolpidem, the same drug product. It has the NDC code and it goes to the right and it shows that the amount Medicaid reimbursed to Massachusetts in that particular period of time was $4464.

So, what I now know from these two data sources is that Teva submitted coded Zolpidem as an eligible drug and that the state did what you'd expect it to do, which was cover it.

Now, if, in fact, Ms. Conrad's theory of fraud were true, you would be able to go to another database and figure out whether or not this is fraudulent or not.

Now, there's a database called the Orange Book. This is the Federal Government's, the FDA's listing of all authorized and approved drugs. And here what we have is, because Zolpidem is an approved drug, you can go into a drugstore and get it, you actually see -- and I've blown up a little copy of that page. You'd see that Zolpidem on the right-hand side is in the Orange Book, but if you looked in the Orange Book for a product that was on the first two lists, represented by the company as a drug and reimbursed and you didn't find Zolpidem, you would be able to make your alleged case of a fraud. And, indeed, the plaintiffs have argued that there are certain vitamins and minerals and supplements, and

whatever, that are not listed in the official list of government drugs and, yet, we've submitted for reimbursement and have been paid.

This is the essence of having public sources available, and it's no surprise that this is how Ms. Conrad found this, because she's not a typical whistle-blower. She didn't work for one of the companies. She didn't have inside information. In fact, she worked for the government. She worked for the Medicaid organization in healthcare. She's effectively like an expert for the government.

Now, one argument that the plaintiff -- the relator makes here is she says, Well, the Orange Book only tells you what is a drug. It doesn't actually tell you what isn't a drug and, therefore, it's not really a public source.

That's kind of like saying if you were trying to identify voter fraud in the election and you wanted to see if someone was not a registered voter, that you wouldn't be able to use the list of registered voters. You'd have to go to a list of non-registered voters and, obviously, we don't have such lists. The way you determine if a voter is not registered is you see if he's on the list to vote, registered voters, in the same way that if you want to know whether a drug is not allowable, not approvable, not reimbursable, is you see if it's not on the Orange Book.

Now, I would suggest, your Honor, that this is

exactly the kind of publicly-available information that is appropriate. In *Organon*, you found that the public disclosure bar did not block the case with respect to off-label marketing because the FDA warning letters did not even concern the fraudulent conduct at issue, and then when the defendant said, But there's lots of claims data that they could have looked at, you said in your opinion, But I don't even know what the claims data relates to. I don't know what the information is. It's not defined, but here it's very defined.

So, in the wake of this publicly-available information, what are the other two arguments that the relator makes? Number one, she says, Well, the First Circuit has a very, very narrow view of what administrative reports are, and these are not administrative reports.

Well, with respect, she's wrong about that. In fact, the First Circuit was part of a circuit split between the First Circuit and the Ninth Circuit on the very subject of what these reports are. And in *Ondis*, what the Court said was even responding to a FOIA request, which is a government official literally responding to a document request and piling up a bunch of documents and handing it to the other side, even that constitutes an administrative report.

It doesn't require, as the relator suggests, any kind of analysis or synopsis. That's precisely what the Ninth Circuit had said, and the First Circuit in *Ondis* had disagreed

and the Supreme Court broke the tie in *Schindler* and in *Schindler* the Supreme Court made very clear that, in fact, we have a very general approach, a broad approach, to public disclosure and administrative reports should be looked at in the broadest sense of the term "report."

What does the word "report" mean? According to the Supreme Court in *Schindler,* it simply is anything that gives information, anything that provides a notification. Because as the Court said, quote, "This broad ordinary meaning of 'report' is consistent with the generally broad scope of the FDA's public disclosure bar."

So -- and just to point out, your Honor, in the wake of the *Schindler* decision, district courts around the country have found that databases, for example, of tax information -- the Southern District of New York in the United States, ex rel. *Rossner* case, 739 F. Supp. 2d, 396, made very clear in the wake of *Schindler* that even a searchable database of tax information was a public disclosure and an administrative report, and the Northern District of Illinois in the *Feingold* case, 2011 WestLaw 1155250, made very clear that -- I'm sorry, 2001 -- statistical printouts from HCFA, which is the forerunner to CMS, statistical printouts are administrative reports.

So, what we would ask --

THE COURT: Do these reports that you're showing me

have dates?

MR. LEFKOWITZ: Yes. All of these reports -- they are reports at any point in time. There are published --

THE COURT: With the time --

MR. LEFKOWITZ: Correct.

THE COURT: -- shown on them?

MR. LEFKOWITZ: And they tell you, in fact -- in fact, there are -- they tell you the period that they are covered. Some of them are covered by a quarter. Some of them are covered by a year. And when you look at the -- you can tell exactly the timeframe that the submission and the reimbursement was made.

THE COURT: And the other question I have is the prior printout showed just Zolpidem and here we have something more specific, Zolpidem tartrate, also the size of the --

MR. LEFKOWITZ: Correct. So --

THE COURT: -- drug.

How do I know that it's Zolpidem tartrate that is shown on this chart and not Zolpidem --

MR. LEFKOWITZ: Your Honor, because the drug data utilization report is actually an online -- and without printing out thousands of pages I couldn't bring it in. I've actually prepared for your Honor what is effectively a demonstrative and I've tried to consolidate, but all of the specific drugs that get reimbursed by name are listed on the

drug data reports and all of the drugs that either are allowable or not you can determine from the Orange Book.

Now, I would simply make one final point on this and then move on to her other argument, which is what she devotes most of her briefing to.

I would suggest, your Honor, that unlike a response to a FOIA request, which is simply just a collection of documents which may or may not tell a particular story, these are actually very clearly articulated databases that are directly relevant to the very issues in this case.

Now, what does Ms. Conrad say in response to all of this? She says she deserves credit for piecing this alleged fraud together.

But, your Honor, as the *Ondis* court made very clear, and I'm quoting, "expertise that enables a relator to understand the significance of publicly-disclosed information without more is insufficient to qualify him as an original source."

And, indeed, your Honor, the investigation in *Ondis* could clearly have been deemed the same kind of archeology that we have here. There, the relator went through public records and unearthed fraud that the government had not yet discovered.

And, frankly, your Honor, here there's one other critical document I want to show you. In 2001, more than a

decade ago, CMS, HCFA actually it was called at the time, but certainly Health and Human Services, put out a press release in which they said, They have been working together with the FDA to develop a system of identifying the non-drug products that erroneously have NDC numbers associated with them. To that end, we will be matching active records on the FDA listed and pending files to the active records on the Medicaid drug rebate initiative to identify any records that do not match and, therefore, do not meet the definition of covered outpatient drug.

Your Honor, basically, the essential theory of Ms. Conrad's case, the essential theory of her fraud, was disclosed in a narrative, wholly apart from the fact that all of the underlying data is publicly available, and I would submit that what she did was precisely what she claims to have done, a lot of archeology.

And in that respect, your Honor, I would submit that her function is really in the nature of an expert witness for the government, a consulting expert. She was brought in because of her expertise and she worked with the government, and she may well have performed a valuable service, but that valuable service is not the service that the statute rewards with respect to being a relator.

One final case I just want to cite for you here. It's an important D.C. Circuit case called *United States, ex*

rel. Springfield vs. Quinn, 14 F.3d 645, and the quote is really directly on point, your Honor. "There may be situations in which all of the critical elements of fraud have been publicly disclosed, but in a form not accessible to most people. For example, engineering blueprints on file with a public agency. Expertise in the field of engineering would not in and of itself give a qui tam plaintiff the basis for suit when all the material elements of fraud are publicly available, though not readily comprehensible to non-experts."

Your Honor, that is precisely the situation we have here. So, on the jurisdictional point, I would submit, your Honor, that she fails the public disclosure bar.

I want to just make two final points and then I'll sit down.

One is, there's a lot of briefing about the statute of limitations here and that would only be relevant if you allow the case to proceed. We have submitted that for most of the defendants, the first unsealed complaint, which was in 2009, applies and, therefore, the statute of limitations should bar any claims going back before 2003, six years earlier.

There's a lot of briefing about Rule 15(c)(1)(A) and discussion about how Judge Saris in the AWP cases, the *Ven-A-Care* case, applied Rule 15(c)(1)(A). Well, it's true she did, but she did that without taking into account the fact

that the statute changed. It actually changed after briefing and argument in that case just shortly before she issued her opinion, and I'm not sure what happened there, but the statute changed and the statute now makes very, very clear that if the -- that the relation that is only when the government is the party. That's the statute that was changed in May of 2009. So, all of the relator's arguments about 15(c)(1)(A) are to no avail.

And, indeed, although this Court has not yet had occasion to address this issue since the amendments, the two courts in the country that have looked at this, one in the District of Columbia and one in Indiana, and we cite them, 2011 WestLaw 1791710 and the first is 608 F.3d 871, make very clear that the 2000 amendments have held that the relation back only applies to government.

And so, what that leaves is 15(c)(1)(B), and even Judge Saris recognized in her opinion that under that provision, notice is the lighthouse, and your Honor will recall that you decided a case several years ago, *In Re Exchange Securities Litigation*, where you held that fraud claims based on an allegedly fraudulent SEC registration statement were time barred under (c)(1)(B). Why? Because the earlier complaint made no reference to the particular IPO at issue.

Notice is the lighthouse under (c)(1)(B) and,

obviously, when you don't have notice because of the ceiling of the prior complaints, you can't qualify. Judge Saris was deciding the case under a prior version of the False Claims Act which doesn't apply here.

The last and final point I want to make has to do with the cough-cold products, and it's a very small point, your Honor. In the Healthpoint case, the defendant was arguing to you that you should rely on the Weiss list. It's a 1987 list by the FDA of the status of various drugs subject to the DESI review, and you said you're not going to take that really into account because you said, and I'm quoting, "The several FDA lists and categorizations do not, *a priori*, establish that Granulex was eligible for reimbursement. The lists merely describe Granulex as not reviewed and, therefore, may or may not be subject to DESI notices."

Your Honor, that's because if you look on the chart here -- this is exactly from that Weiss list. It described that the category that we were talking about there was for a tentative review that indicates that they may or may not be subject to DESI. And so, we understand why your Honor said I'm not going to rely on that Weiss list for anything. It doesn't tell me.

But the category that we're talking about, Category A on the Weiss list and, indeed, in particular Category A-11, if you look at the next page, makes clear that Category A-11 are,

in fact, drugs that are under review by the cough-cold panel and if they are under review by the cough-cold panel, then it by law means no NOOH has been issued.

We will rest on our briefs for the rest of that cough-cold discussion. I just wanted to clarify because your Healthpoint decision came out after the briefing.

THE COURT: Thank you very much.

MR. LEFKOWITZ: Thank you, your Honor.

THE COURT: Mr. Roddy.

MR. RODDY: Your Honor, I'd like to begin by putting the case in context, because whether it's *Ondis* or *O'Keefe* or any of the First Circuit or District Court cases that have interpreted the bar, the key principle that the First Circuit has emphasized is that the public disclosure bar has to be applied within the larger context of the purpose of the False Claims Act, and the purpose of the bar itself is to protect the government from so-called parasitic opportunists who do nothing more than copy information that's in the public domain from a qualifying source, and that's something I'd like to talk to you a little bit about, and then throw something at the government asking for some money back without contributing anything of value.

But here, the government, which is the entity that is in the best position to determine whether the relator provided anything of value whatsoever, has already acknowledged that

the relator has provided substantial value by paying for the relator's share on the $85 million of settlement money that's already recovered from the five defendants that have settled, finally, and the government recently on a docket entry indicated that it has reached a tentative settlement with Healthpoint on its $90 million claim. So, now the defendant --

THE COURT: What is the effect on my decision of that?

MR. RODDY: That indicates, your Honor, that the entire premise of the overarching theme that the defendants argue here that the public disclosure bar should prevent this parasitic opportunist from pursuing her claim is a faulty premise because she has clearly given the government something of value --

THE COURT: Can I disagree with the government?

MR. RODDY: I'm sorry?

THE COURT: Can I disagree with the government?

MR. RODDY: Of course you can, your Honor.

THE COURT: Okay.

MR. RODDY: But in that context, I think that the important element to keep in mind in interpreting every aspect of the bar is that the government has already determined that the bar shouldn't be invoked against Ms. Conrad. Compare that to the *Petite* case in which --

THE COURT: But it's different drugs also, isn't it, that may have had different databases?

MR. RODDY: I don't believe that's correct, your Honor.

THE COURT: It's the same Zolpidem, and such? I thought each of the defendants had different drugs?

MR. RODDY: Different drugs, but a single universal theory, which is that the drugs that are listed are unapproved.

THE COURT: Yes, but are they all listed in the same way?

MR. RODDY: Well, that's actually my next point, your Honor.

The way they're listed -- the X plus Y equals Z analysis that the defendants are premising their argument on requires that under the False Claims Act, the first indicator, which is the state utilization data tables and -- which shows the amounts that were paid, and the data tables that show the actual drugs that were submitted to CMS as so-called approved drugs, the notion that those data tables, which even the defendants admit in their brief are unadorned data tables, are reports.

Now, I notice that in the presentation they're titled "reports," but that's not what CMS calls them. The word "reports" appears nowhere in any of those data tables. And if

I could hand up, your Honor, the actual report from Exhibit 8, it looks nothing like what you just saw.

(Attorney Roddy hands document to the Court.)

THE COURT: Mr. Lefkowitz did tell us that he had abstracted that line from the rest and highlighted it.

MR. RODDY: I agree, your Honor. I believe he also added adornments, titles, colors, indicators.

There's no report, so to speak, which requires an actual instruction manual as Exhibit 7 in the defendants' submission. In order to interpret that database, you need an instruction manual that tells you what all these things actually stand for. So, with respect to the general notion of what a report is, I think that that fails that test.

Secondly, the bar --

THE COURT: What, then, is the standard? I mean, here I gather the relator was not intimately involved in the fraud and then reported it. She read whatever the reports or non-reports were and deduced from what she read, based on her understanding of these materials, that there might be an issue.

Now, why is it not -- why is her report not a public -- a prior public report, when anybody else reading the same thing she read can also come to the same conclusion she did?

MR. RODDY: I think there are two responses to that,

your Honor.

But first I'd like to say that the False Claims Act essentially has two categories of relators that it imposed to a relator's award: Someone who is inside the sausage factory and sees the fraud and reports it and someone who doesn't have that kind of direct information but obtains, as Ms. Conrad did, not reports, not public disclosures, but information that is gleamed from numerous sources, pieced together and put into a package and presented to the U.S. Attorney.

There's a distinction -- and the cases all talk about this *Springfield*, which defendants' counsel mentioned in particular -- that there is a distinction to be made under the bar between information that is in the public domain and information contained in administrative reports as defined under the statute.

Two points on that score, your Honor. The first one is that defendants say that *Schindler* and *Ondis* describe a report as "anything that gives information." That language can only be properly construed as dicta taken out of context, because *Schindler* talked about FOIA responses being reports for a number of specific reasons. I won't detail those now.

Similarly, *Ondis* looked at the procedure that the government went through in responding to a FOIA request and determined that that would properly be construed to be a report, but a clock, a stop sign, an image of a graphic, all

of those things give information. They are anything that gives information. They cannot be construed to be reports and they certainly can't be construed to be reports, nor can these unadorned data tables within the context of the FCA.

Ondis and *Duxbury* talk about the need to "avoid an interpretation of the bar which is so overbroad as to prohibit cases that are productive private enforcement suits. We eschewed reading an exclusion in *Rost* that did not have textual support and resulted in discouraging productive private enforcement."

Well, here, the operative language in the statute is the information -- here we're talking about the transactions, because there's no argument that allegations are disclosed -- that is disclosed in an administrative report.

So, disclosure is an affirmative representation and disclosure in an administrative report means that -- for example, the Orange Book and the NDC directory, which defendants argue don't contain any indication that their drugs are approved; therefore, they disclose that their drugs are unapproved.

Well, the text of the statute requires an affirmative representation and disclosure. Defendants argue for a public omissions bar. If it's not there, then you must be able to figure out that something else has happened.

Well, that may be true, but it's not within the

context of the statute's bar. The statute is very limited and exclusive, as the Court said in *Blank vs. Raytheon*, and if it doesn't meet -- that is, the situation doesn't meet the exact criteria set out in the statute, you can't properly deem such an omission to be a disclosure contained in an administrative report.

Now, the defendants claim that there are three cases that held data files like CMS's to be administrative reports. *Jamison* is the first one. There the Court notes at the outset the purpose of the bar is to prevent parasitic suits, and in that case there were ten reports, an OIG fraud report among them, and a number of other specific disclosures, affirmative representations. There are no unadorned data files in *Jamison*.

Rossner, same thing, but *Rossner* found -- and this is particularly interesting here. On a Website with tax histories, it de-qualifies a report because the Website is easily navigable, and I challenge you to navigate that site, and does not present raw unanalyzed data, which is exactly what we have here. Rather, it presents -- and the defendants criticized the relator's notion that some synthesis is necessary in order to produce natural reports. It presents synthesized tax benefit histories. So, that doesn't really seem to fit the bill here either.

And then, finally, there's *Feingold*, which notes at

the outset that the jurisdictional bar is raised only where the transactions for the allegations of fraud, and it highlights this, as opposed to mere innocuous information that has been publicly disclosed.

So, again, there are no cases that defendants cite that are anything like this case, and to stretch the definition of "administrative report" beyond the boundaries that have already been established by the First Circuit in this circumstance would create the first case that we would be aware of where the government has already recovered somewhere in the vicinity of $100 million, paid the relator's share as a result, and then the case was subsequently dismissed based on the public disclosure bar, and this is where we get to the intent of the bar.

What would be the purpose of the bar that is being served there? So that the defendants could get away with not having to pay the kind of money that their six-settling cohorts have already agreed to pay the government. So, their argument actually runs counter to the entire intent and purpose of the FCA and it is in that context that we believe all of these items have to be construed.

Finally, your Honor, just observe that the one case that the defendants argue shows an omission to be equivalent to a disclosure is the *Dunlevy* case out of the Third Circuit, was subsequently abrogated by *Graham County*, a U.S. Supreme

Court case, and it's the only case we know of that talked about an omission being tantamount to a disclosure. The omission was the last in a series of public -- unarguably, public disclosures that reveal the allegations of fraud.

There is no such case in the First Circuit that doesn't observe the plain text of the statute as I've just articulated and, again, I reiterate that the First Circuit does repeatedly emphasize the importance of observing the bar's limits to avoid an overbroad meaning.

THE COURT: Thank you.

MR. RODDY: Thank you, your Honor.

MR. LEFKOWITZ: May I just have two minutes?

THE COURT: So, what is a report?

MR. LEFKOWITZ: What was that?

THE COURT: What is a report?

MR. LEFKOWITZ: Your Honor, I'm glad you're starting there because I want to just read to you from *Schindler*. The Court in *Schindler* started out by saying -- I took the wrong page from *Schindler*. I apologize, your Honor.

THE COURT: It's okay.

MR. LEFKOWITZ: Correct.

Here's what *Schindler* says: "Kirk argues that reading 'report' to mean 'something that gives information' would subsume the other words in the phrase 'report, hearing, audit, investigation.'

"We are not persuaded that we should adopt a 'different, somewhat special meaning' of 'report' over the word's primary meaning. Indeed, we have cautioned recently against interpreting the public disclosure bar in a way inconsistent with a plain reading of its text. In *Graham County* we rejected several arguments for construing the statute narrowly, twice emphasizing that the sole 'touchstone,' the sole 'touchstone,' in the statutory text is public disclosure."

Now, what is public disclosure? Your Honor, on that very database that counsel referred you to, what he didn't show you was the first two pages of the database which have the instructions, the key, and the key says this is how you utilize it. One period is period covered. The next column is the product FDA name. The next column is the units reimbursed, the number of prescriptions, the total amount reimbursed under Medicaid. Yes, it is a comprehensive data file and as in many of these cases, it does require someone to take some effort, but the key is it is publicly disclosed.

And I'm not suggesting that the relator didn't provide assistance to the government in these cases that settled, but as your Honor pointed out, those were different cases involving different products and, indeed, in part, involving different theories.

Here we have a theory that doesn't have to do with a

drug that was very specifically identified on a federal register notice as ineligible for funding which, in fact, the party tried to get funding for. We're dealing with situations where they're alleging that Medicaid can never reimburse for anything that's not a covered outpatient drug, and we know, your Honor, that that's not the case because the statute says Medicaid must provide for home health services, and we know that the CMS has said certain types of over-the-counter dietary supplements, while they can't be eligible under one part of Medicaid, can be eligible for another part. There are ambiguities here throughout the statute, but the key is that the elements in this case are not the same as the elements in that case.

And, your Honor, no one is suggesting here that if this case is dismissed, and there is, in fact, a fraud that the government is troubled by, they can't bring a case or that a true original source, a true whistle-blower, couldn't bring a case.

The question is simply whether the statute is intended to reward people who basically read a roadmap from a government press release in 2001, go out -- and because they have expertise, because they've worked in the government healthcare agency, go out and collect this data and then bring a case. They may have helped uncover frauds that the government decided to pursue. That's fine. But the

government has not decided to pursue this.

And, finally, the last point, with respect to counsel's argument that, Well, what we're arguing for is a public omissions bar, not a public disclosure. The fact is, if you want to know what a lawful or an unlawful drug is, you look at the list of lawful drugs.

I don't think I've ever used Latin in an argument, but I think the phrase is *expressio unius*, if I remember from 30 years ago. That's how you know whether a drug is not lawful. You don't have anywhere in the world a listing of everything that is not a lawful drug.

Thank you, your Honor.

THE COURT: Thank you.

Does anybody else want to be heard? Do you?

MR. DOVE: Yes, your Honor.

THE COURT: Go ahead.

MR. DOVE: Good afternoon, your Honor.

My name is Ron Dove and I represent defendant Healthpoint. I just have a few minutes on this.

Your Honor, Healthpoint joins in the motion that Mr. Lefkowitz just argued, but we also separately move to dismiss the relator's claims as to two Healthpoint drugs, Panafil and Acu-Dyne.

The relator claims that Healthpoint violated the False Claims Act by misrepresenting that Panafil and Acu-Dyne

were covered outpatient drugs under Medicaid when neither drug had been approved by the FDA, but a drug does not have to be approved by the FDA to be reimbursed by Medicaid. The Medicaid statute makes clear that a particular drug can qualify as a, quote, "covered outpatient drug" if, first, the drug was commercially used or sold in the United States before October 10th, 1962, or is identical --

THE COURT: Before 1962?

MR. DOVE: Before October 10th, 1962, or is identical, similar or related to such a drug. And, second, the drug has not been the subject of a DESI notice or new drug determination by the FDA.

And, indeed, your Honor recognized this in its earlier decision involving the product Xenaderm where you stated that "drugs not approved by the FDA are not categorically precluded from Medicaid and Medicare reimbursement."

So, under this regulatory definition, it was reasonable and certainly not frivolous or reckless for Healthpoint to have determined that Panafil and Acu-Dyne were IRS to the pre-1962 drug Panafil.

And why is this? There's two things I want to highlight, your Honor. First, the relator concedes that a form of Panafil was introduced to the market on or before 1956 by another company called Rystan and that puts it in the

pre-1962 legacy drug category.

And then second, and most importantly, your Honor, it is undisputed that the FDA did not determine Panafil or Acu-Dyne to be new drugs until September 2008, after the period for which the relator seeks relief, and that, your Honor, is the biggest difference between this motion and the one the Court decided earlier with regard to Xenaderm, which was the case in which the United States intervened. The United States has not intervened against these two drugs.

The Court may recall that in that case there were two FDA notices from the 1970s that the government argued put Healthpoint on notice that Xenaderm was less than effective and, thus, not subject to reimbursement.

You know, we don't agree with that, but the fact that Xenaderm was arguably subject to prior DESI notices was a key factor in the Court's decision in that case.

We're in contrast in this case. As Mr. Lefkowitz said -- you know, pointed to the differences in this case. The relator has pointed to no such prior notices, none whatsoever with regard to Panafil and Acu-Dyne.

So, the bottom line, your Honor, is that the relator's claim that Panafil and Acu-Dyne were not covered outpatient drugs under the Medicaid statute is just simply wrong as a matter of law, and the relator has also not alleged any facts that would suggest that Healthpoint intentionally

did anything wrong or acted with reckless disregard, which, as you know, is the minimal level of scienter under the False Claims Act.

So, for these reasons, your Honor, and those that we laid out in detail in the briefs -- I won't rehash those -- we respectfully request that the Court grant Healthpoint's motion to dismiss. Thank you.

THE COURT: Thank you.

MR. RODDY: Your Honor, there are two points that Healthpoint is essentially arguing here. I'd like to take the second one first, and that is the notion that it acted reasonably with respect to looking at the DESI or non-DESI circumstances of the drugs that were being marketed. I believe that that has already been determined adversely to them in your ruling in the original Healthpoint motion.

Secondarily, the main point that Healthpoint tries to argue is that Panafil and Acu-Dyne are identical, related or similar to the previously-marketed drugs. Two things on that score.

If they were identical, related or similar, it's curious that in 2004 and in 2006 Healthpoint marketed the Acu-Dyne spray and the Panafil spray as, I quote from their press release, "a new pump stray delivery system in which a patent application is pending."

As a matter of law, a brand-new drug which the

proponent is seeking a patent for cannot be identical, related or similar to a drug that was marketed 30 years prior.

Secondarily, we do not concede that these drugs were IRS in any respect to Panafil, the original 1956 Rystan Panafil or the Panafil-White, and on Panafil-White the determinative marker is October 10th, 1962.

Healthpoint says that their -- this particular drug was introduced around 1962. They submitted I believe in their materials, which I believe were inappropriate, anyway, because this is a 12(b)(6) motion to dismiss, a PDR from 1964, and just for the Court's reference and to take judicial notice, there's a PDR from 1962 in which that particular drug does not appear. So, it is, at best, a question of fact whether that particular drug was even marketed prior to the deadline, and I believe that also with respect to the spray elements of the two, of Panafil and Acu-Dyne, it as a matter of law cannot be stated that they're identical, related and similar to the prior drugs if they are marketed as new drugs in which a patent application is pending. Thank you.

THE COURT: Thank you. Anybody else?

(No response.)

THE COURT: Well, I thank you all. I hope the audience had a good time.

MR. LEFKOWITZ: Thank you, your Honor.

(Adjourned, 3:24 p.m.)

C E R T I F I C A T E

I, Catherine A. Handel, Official Court Reporter of the United States District Court, do hereby certify that the foregoing transcript, from Page 1 to Page 39, constitutes to the best of my skill and ability a true and accurate transcription of my stenotype notes taken in the matter of Civil Action No. 02-11738-RWZ, United States of America, ex rel Constance A. Conrad versus Abbott Laboratories, Inc., et al.

November 16, 2012 /s/Catherine A. Handel
Date Catherine A. RPR-CM, CRR